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10/562,215

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Klaus Junk

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WASHINGTON, DC 20005

EXAMINER

HICKS, VICTORIA J

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,215	<b>Applicant(s)</b> JUNK, KLAUS	
	<b>Examiner</b> VICTORIA HICKS	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>definition of "receive"</u>            |

## DETAILED ACTION

**This action is in response to the amendment filed on April 10, 2009.**

### *Response to Arguments*

Applicant's arguments filed 4/10/09 have been fully considered but they are not persuasive.

Applicant failed to amend to abstract of the application to overcome the Examiner's previous objection. The objection to the abstract has therefore been maintained.

In response to applicant's argument that the Patnode reference does not teach fenestrations are for an incise film or for the reception of a means of cover, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The fenestrations taught by Patnode are **capable of** being used with an incise film. The incise film can simply be placed over the fenestrations taught by Patnode.

In response to the Applicant's argument that the fenestrations taught by Patnode are designed to allow a limb to pass therethrough and a fenestration for an incise film would inhibit the passing through of a limb as is required by Patnode, the Examiner respectfully disagrees. An incise film is capable of being used with the fenestrations taught by Patnode, while still passing the limb through the fenestrations. For instance,

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with the patient's limb placed as taught by Patnode in Figure 5, one could easily place an incise film over the limb (66) that is passed through the fenestration (covering the fenestration), in order to further protect the surgical area. This placement of an incise film still permits the passing through of a limb (through the fenestration). The same such placement could be applied to the fenestrations (28, 29) that are cited in the rejection below. Covering the fenestrations taught by Patnode would therefore, not make the drape of Patnode inoperable. Applicant only claims fenestrations **capable of use** with an incise film.

In response to Applicant's argument that the transparent cover means of Williams would interfere with the intention of Patnode to allow the passage of the patient's limb therethrough, the Examiner respectfully disagrees. Patnode does not teach passage of a patient's limb therethrough. In contrast, in claim 1, for instance, Patnode teaches that the fenestrations are "adapted to **receive** a limb therethrough." This language does not require that the entire limb of the patient be able to pass completely through the fenestrations taught by Patnode. The term "receive" is defined as "to hold, bear, or contain." For purposes of clarification, a definition of the term "receive" has been enclosed with this action. The fenestrations taught by Patnode are able to hold, bear, or contain ("receive") a patient's limb while covered by the transparent cover means taught by Williams. Please refer to the suggested placement of the limb and cover means that is described above.

### ***Specification***

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In order to avoid the use of legal phraseology in the abstract, the term "means" should be removed from this section of the application.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Patnode et al. (US patent 5,143,091).

In regards to claim 1, in Figure 2, Patnode et al. Teaches a surgical drape with a first fenestration (28) and at least one further fenestration (29) which is capable of being used for the reception of a means of reference protruding from the level of the drape's surface, which is identifiable for a 2- or 3-dimensional measurement system.

In regards to claim 14, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). In Figure 4, Patnode et al. teaches that the two means of cover (24), which overlay the two fenestrations (28, 29), are placed equidistant from the center of the drape (20). In column 5, lines 56-57 Patnode et al. teaches that the fenestrations (28, 29) and thus the means of cover (24) have a spacing of 300-500 mm (30-50 cm), which would make each means of cover (24) spaced a distance of 15-25 cm from the center of the drape (20), which falls within the claimed distance range.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-4, 11, & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patnode et al. (US patent 5,143,091) in view of Williams et al. (US patent 5,490,524).

In regards to claim 2, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach a means of coverage that is transparent for the radiation emitted by a measurement system. In column 3, lines 44-45 Williams et al. teaches an analogous device with a means of cover (40), which could be placed in the area of coverage of the means of reference, that is transparent. It would have been obvious for one having ordinary skill in the art at the time of invention

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to modify the surgical drape taught by Patnode et al. with the means of cover taught by Williams et al. because that element is known to make the surgical drape taught by Patnode et al. applicable for use with measurement systems.

In regards to claim 3, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). In Figure 2, Patnode et al. teaches a second fenestration (29). Patnode et al. does not teach a means of cover that is firmly bound or able to be bound with the drape. In column 4, lines 11-15 Williams et al. teaches an analogous device in which the means of cover (40) is bound to the drape by ultrasonic welding, heat sealing, gluing, or using double-sided tape (adhesive strips) along the entire perimeter (42) of the window (40). In figure 2, Williams et al. teaches that the perimeter (42) of the window (40) is aligned with the perimeter of the fenestration (24). It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the bound means of cover taught by Williams et al. because that element is known to effectively secure the means of cover to the drape.

In regards to claim 4, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach a means of cover that is made of a flexible material. In column 4, lines 25-29 Williams et al. teaches an analogous device in which the means of cover (40) is made of a flexible material. It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the flexible means of cover taught by Williams et al. because that element is known to allow the surgical drape taught by

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Patnode et al. to fit over varying sizes and shapes of targeting devices, as taught by Williams et al. in column 4, lines 27-29.

In regards to claim 11, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach that the drape is attached firmly to a means of cover. In column 4, lines 12-14 Williams et al. teaches an analogous device in which the means of cover (40) is attached firmly to the opening (24) on the surface of the drape (10) by the technology of ultrasonic welding. It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the attachment method taught by Williams et al. because this element is known to prevent the introduction of non-sterile material to the sterile environment created by the surgical drape taught by Patnode et al.

In regards to claim 16, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach at least one means for cover for the further fenestration. However, in column 3, lines 44-45 Williams et al. teaches an analogous device with a means for cover (40) for the fenestration, which could be used for a means of reference protruding from the level of the drape's surface, which is identifiable for a 2- or 3- dimensional measurement system. It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the means for cover taught by Williams et al. because that element is known to make the surgical drape taught by Patnode et al. applicable for use with measurement systems.



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5. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patnode et al. (US patent 5,143,091) in view of Auerbach et al. (US patent 7,316,233).

In regards to claim 5, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach a means of cover that features a form that is elongated or able to be elongated. In Figure 1, Auerbach et al. teaches an analogous device with a means of cover (3) that is elongated in a cylindrical form with a closed end (32) on the side facing away from the drape (1). It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the elongated means of cover taught by Auerbach et al. because this element allows the surgical drape taught by Patnode et al. to be used to create a sterile barrier between a surgical site on an extremity and the remainder of the patient's body, Auerbach et al. teaches in column 3, lines 12-16.

In regards to claim 7, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach a means of cover with at least one means to reduce the length of the means of cover. In column 1, lines 53-56 Auerbach et al. teaches an analogous device in which the means of cover (3) has an adjustable length. In column 5, lines 60-65 Auerbach et al. teaches that the means of reduction for the reduction of the length is located along the means of cover (3) away from the remainder of the bottom end of the drape (2). Auerbach et al. further teaches that the means of reduction can include a rolling pattern that would allow the upper end to be stretched firmly and smoothly while avoiding creases or other distortions. It would have been obvious for one having ordinary skill in the art at the time of invention to modify the

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surgical drape taught by Patnode et al. with the means of reduction taught by Auerbach et al. because this element is known to allow the surgical drape taught by Patnode et al. to be adjustable to accommodate various anatomical extremities, as Auerbach et al. teaches in the abstract.

6. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patnode et al. (US patent 5,143,091) in view of Greco (US patent 5,312,385).

In regards to claim 6, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach that the means of cover features at least one means of reduction. In Figure 1, Greco teaches an analogous device in which the means of cover (2) features along the surface at least one means of reduction (3), for the reduction of the perimeter of the means of cover (2) approximately vertically to the longitudinal axis from the bottom end to the upper. It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the means of reduction taught by Greco because this element is known to allow the surgical drape taught by Patnode et al. to be effectively secured to objects of various sizes.

In regards to claim 8, Patnode et al. and Greco teach the apparatus of claims 1 and 6 (see rejection of claims 1 and 6). Patnode et al. does not teach that the means of reduction are realized in the form of removable adhesive strips or simple cords. In column 4, lines 48-52 Greco teaches an analogous device in which the means of

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reduction (3) is realized in the form of a drawstring, which is a simple cord, or adhesive tape.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kienzle III et al. (US patent 6,697,664).

In regards to claim 9, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach a means of cover that features pre-shaped moldings on its upper, drape-opposing end for the reception of shapes of the means of reference. In column 5, lines 19-26 Kienzle III et al. teaches an analogous device in which the means of cover includes pre-shaped moldings that are similar in size and shape to the means of reference, for the reception of the means of reference. It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the means of cover with pre-shaped moldings for the reception of the means of reference because this element is known to ensure that the means of cover fits flat and flush against the means of reference so that their positions may be accurately determined by a measurement system, as Kienzle III et al. teaches in column 5, lines 22-26.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patnode et al. (US patent 5,143,091) in view of Sklar (US publication 2002/0069882).

In regards to claim 10, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach a means of cover that is able to be

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sterilized. In [0019] Sklar teaches an analogous device that includes a means of cover that is able to be sterilized by gamma radiation. It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the means of cover that is able to be sterilized taught by Sklar because that element is known to make the surgical drape taught by Patnode et al. reusable.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patnode et al. (US patent 5,143,091) in view of Teves et al. (US patent 6,820,622).

In regards to claim 12, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode does not teach that the means of cover has the capacity to be inflated. In column 3, lines 52-54 Teves et al. teaches an analogous device with a means of cover that has the capacity to be inflated, which would avoid the formation of creases and distortion of the radiation falling on the means of reference or reflected therefrom. It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the inflatable means of cover taught by Teves et al. because this element is known to provide a smooth platform for surgical tools, such as means of reference, as Teves et al. teaches in column 5, lines 60-65.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patnode et al. (US patent 5,143,091) in view of Rubenstein et al. (US patent 5,417,225).

In regards to claim 13, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. does not teach that the fenestration of the drape has a minimum outside diameter of 10-50, preferably 25 cm. In column 5, lines 44-46 Rubenstein et al. teaches an analogous device in which the fenestration has a diameter of 15 cm, which falls within the claimed diameter range. It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the fenestration diameter taught by Rubenstein et al. because this dimension is known to allow the surgical drape taught by Patnode et al. to be compatible with measurement and imaging systems as taught by Rubenstein et al. in column 5, lines 47-51.

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patnode et al. (US patent 5,143,091) in view of Idris (US patent 4,869,271).

In regards to claim 15, Patnode et al. teaches the apparatus of claims 1 and 14 (see rejection of claims 1 and 14). Patnode et al. teaches in Figure 2 that the means of cover (24) are located equidistant, to the left and right, from the center of the incise film (20). Patnode et al. does not teach that the means of cover are arranged at a distance approximately 40 cm left and right in a perpendicular distance from the center of the incise film. In column 2-3, lines 63-6 Idris teaches an analogous device in with the means of cover (24) is located 30 inches (76.2 cm) from the top edge of the film (10) which is 70-140 inches (177.8-355.6 cm) in length. Therefore, the means of cover (24) can be placed approximately 40 cm from the center of the incise film, depending on the

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length of the film (10). It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the dimensions taught by Idris because this arrangement is known to allow the surgical drape taught by Patnode et al. to be cover more of a patient when in use, as Idris teaches in column 3, lines 2-6.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Patnode et al. (US patent 5,143,091) in view of Scrivens (US patent 4,027,665).

In regards to claim 17, Patnode et al. teaches the apparatus of claim 1 (see rejection of claim 1). Patnode et al. (US patent 5,143,091) in view does not teach an incise film covering the first fenestration. However, Scrivens teaches in columns 6-7, lines 66- 13 an analogous device in which an incise film (70, 71) covers the first fenestration (30, 40). It would have been obvious for one having ordinary skill in the art at the time of invention to modify the surgical drape taught by Patnode et al. with the means of cover taught by Scrivens because that element is known to keep the fenestration in its proper position on the body of the patient, as Scrivens teaches in column 7, lines 9-11.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA HICKS whose telephone number is (571)270-7033. The examiner can normally be reached on Monday through Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/V. H./  
Examiner, Art Unit 3772  
7/16/09

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772